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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,802	02/09/2004	Kari Alitalo	28967/34891.1	9059

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EXAMINER

DANG, IAN D

ART UNIT PAPER NUMBER

1647

DATE MAILED: 08/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/774,802

Applicant(s)

ALITALO, KARI

Examiner

Ian Dang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43-93 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 43-93 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 43-48, drawn to a method of inhibiting Flt4 receptor tyrosine kinase function in a mammalian organism with a neoplastic disease comprising administering an inhibitor of the binding of a Flt4 ligand protein to Flt4 expressed in blood vascular endothelial cells, classified in class 514, subclass 2.
- II. Claims 49-52, drawn to a method for antagonizing the function of Flt4 receptor tyrosine kinase in an organism comprising administering a polypeptide and a pharmaceutically acceptable carrier, classified in class 514, subclass 10.
- III. Claim 53, 55, and 58-60 (in part) drawn to a method of inhibiting neoplastic cell growth in a mammalian subject, classified in class 514, subclass 12.
- IV. Claims 54-55 (in part), 56-57, 58-60 (in part) drawn to a method of inhibiting neoplastic cell growth in a mammalian subject, classified in class 514, subclass 12.
- V. Claims 61-64, drawn to a method of treating a mammal having breast cancer comprising administering an inhibitor of binding between Flt4 ligand protein and Flt4 expressed in cells, classified in class 514, subclass 12.
- VI. Claims 65-70 and 77, drawn to a method for treating a neoplastic disorder comprising of screening a mammalian subject to identify a neoplastic disorder and administering a composition to a mammalian organism, classified in class 514, subclass 12.

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- VII. Claims 71-72, and 74-76, drawn to a method of inhibiting proliferation of blood vessels endothelial cells in a mammalian organism, classified in class 514, subclass 12.
- VIII. Claims 73-76 drawn to a method of inhibiting proliferation of endothelial cells in a human organism having a disease characterized by expression of Flt4 tyrosine kinase (Flt4) in endothelial cells, classified in class 514, subclass 12.
- XIX. Claims 78-80, drawn to a method of inhibiting proliferation of endothelial cells in a human organism having a breast carcinoma characterized by expression of Flt4 tyrosine kinase (Flt4) in vascular endothelial cells, classified in class 514, subclass 12.
- X. Claims 81-84, drawn to a method of inhibiting genesis of blood vessels in a mammalian organism having a disease characterized by expression of Flt4 tyrosine kinase (Flt4) in blood vessels, classified in class 514, subclass 12.
- XI. Claims 85-88, drawn to a method of inhibiting the growth or the metastatic spread of a tumor in a mammalian organism, classified in class 514, subclass 12.
- XII. Claims 89-90, drawn to a method of inhibiting neoplastic cell growth in a human subject, classified in class 514, subclass 12.
- XIII. Claims 91-93, drawn to a method of inhibiting neoplastic cell growth in mammalian subject, classified in class 514, subclass 12.

If one of Groups I-XIII is elected, then election is also required to one of inventions (A)-(E).

The inventions of subgroups (A)-(E) represent the elected invention wherein the inhibitor is one of the following polypeptide:

(A) an anti-Flt4 antibody or a polypeptide comprising an antigen binding fragment

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- (B) an anti-VEGF-C antibody or a polypeptide comprising an antigen binding fragment
- (C) an anti-VEGF-D antibody or a polypeptide comprising an antigen binding fragment
- (D) a soluble polypeptide comprising a fragment of Flt4, wherein the polypeptide and the fragment are capable of binding to human VEGF-C
- (E) a polypeptide comprising an Flt4 binding fragment of human prepro-VEGF-C or human prepro-VEGF-D conjugated to an antineoplastic agent

The inventions are independent or distinct, each from the other because:

The methods of groups I-XIII can be shown to be distinct as they each have different starting materials, methods steps, and/or goals. Each of the methods can be shown to be distinct from each of the products in that the product is either not used by the method or can be used in multiple methods.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of the art and their recognized divergent subject matter, the inventions require a different field of search, (see MPEP § 808.02), and need for non-coextensive non-patent literature search, restriction for examination purposes as indicated is proper. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP 804.01

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ian Dang whose telephone number is (571) 272-5014. The examiner can normally be reached on Monday-Friday 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ian Dang
Patent Examiner
Art Unit 1647
August 14, 2006


BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
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